



0400  
08-23-01

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): Cortese, et al.

SC/Serial No.: 09/843,588

Confirm. No.: 8737

Filed: April 26, 2001

Title: HEMOSTATIC COMPOSITIONS OF  
POLYACIDS AND POLYALKYLENE  
OXIDES AND METHODS FOR  
THEIR USE

PATENT APPLICATION

Art Unit: Unknown

Examiner: Unknown

Customer No. 23910

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence is being deposited in the United States Postal Service with sufficient postage as first class mail in an envelope addressed to **Commissioner for Patents, Washington, DC 20231**, on August 21, 2001.

(Attorney Signature)

D. Benjamin Borson, Ph.D., Reg. No. 42,349

Signature Date: August 21, 2001

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56**

Commissioner for Patents  
Washington, DC 20231

Sir:

It is requested that the information identified in this statement be considered by the Examiner and made of record in the above-identified application. This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56. If this is a continuation, divisional or continuation-in-part application, it is understood that the Examiner will consider all information which was considered by the Office in a parent application. MPEP §609. Such information therefore is not listed herein unless it is desired that the information be printed on a patent issuing from the subject application.

***Enclosed with this statement are the following:***

- ☒ Form PTO-1449. The Examiner is requested to initial the form and return it to the undersigned in accordance with M.P.E.P. §609.
- ☒ A copy of each cited document as required by 37 C.F.R. §1.98. Copies are not submitted of documents previously submitted by the applicant in a parent application from which benefit under 35 U.S.C. §120 is claimed, 37 C.F.R. §1.98(d)(1), with an information disclosure statement submitted in the parent application which complies with the Sept. 8, 2000 or subsequent revision of 37 C.F.R. §1.98(a-c). If any of the cited/submitted documents is in a foreign language, a concise explanation of relevance is provided pursuant to 37 C.F.R. §1.98(a)(3)(i). For foreign language documents cited

in a search report by a foreign patent office, the requirement for a concise explanation of relevance is satisfied by the submission herewith of an English language version of the search report. MPEP §609A(3). If a written English-language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in §1.56(c), a copy of the translation accompanies this statement, 37 C.F.R. §1.98(a)(3)(ii), and satisfies the requirement for a concise explanation of relevance, MPEP §609A(3).

— **PTA Statement under 37 C.F.R. §704(d).** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.

***This statement should be considered because:***

X **37 C.F.R. §1.97(b).** This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:

- (1) It is being filed within three months of the filing date of an application other than a continued prosecution application under § 1.53(d);  
-- OR --
- (2) It is being filed within 3 months of entry of a national stage;  
-- OR --
- (3) It is being filed before the mailing date of the first Office Action on the merits,  
-- OR --
- (4) It is being filed before the mailing date of the first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

— **37 C.F.R. §1.97(c).** Although it may not qualify under subsection (b), this statement qualifies under 37 C.F.R. §1.97, subsection (c) because:

- (1) It is being filed before the mailing date of a FINAL office action, a Notice of Allowance, or an action that otherwise closes prosecution in the subject application, whichever occurs first.

-- AND (check at least one of the following) --

- (1) It is accompanied by a STATEMENT as set forth in 37 C.F.R. §1.97(e).  
-- OR --  
— (2) It is accompanied by the \$180 fee set forth in 37 C.F.R. §1.17(p).

— **37 C.F.R. §1.97(d).** Although it may not qualify under subsection (b) or (c), this statement qualifies under 37 C.F.R. §1.97, subsection (d) because:

- (1) It is being filed on or before payment of the issue fee;  
-- AND --
- (2) It is accompanied by a STATEMENT as set forth in 37 C.F.R. §1.97(e);  
-- AND --

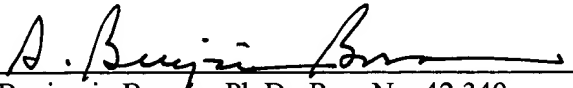
(3) It is accompanied by the \$180 fee set forth in 37 C.F.R. §1.17(p).

✓ **Fee Authorization.** The Commissioner is hereby authorized to charge underpayment of any additional fees or credit any overpayment associated with this communication to Deposit Account No. 06-1325. A duplicate copy of this authorization is enclosed.

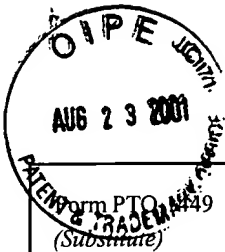
Respectfully submitted,

FLIESLER DUBB MEYER & LOVEJOY LLP

Date: August 21, 2001

By:   
D. Benjamin Borson, Ph.D., Reg. No. 42,349

FLIESLER DUBB MEYER & LOVEJOY LLP  
Four Embarcadero Center, Fourth Floor  
San Francisco, California 94111-4156  
Telephone (415) 362-3800



<b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT</b> <b>BY APPLICANT</b> <i>(Use several sheets if necessary)</i>	Attorney Docket Number <b>FZIO6605US1 SRM/DBB</b>	Serial/Patent Number <b>09/843,588</b>
	Applicant/Patent Owner <b>Cortese, et al.</b>	
	Filing/Issue Date <b>4/26/01</b>	Group Art Unit <b>Unknown</b>

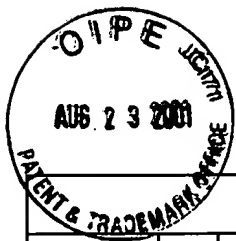
### U.S. PATENTS

Examiner Initial	Patent Number	Issue Date	First Named Inventor	Class	Subclass	Filing Date
	5,356,883	10/18/94	Kuo, et al.	514	54	
	5,502,081	3/26/96	Kuo, et al.	514	777	
	5,621,093	4/15/97	Swann, et al.	536	55.2	
	3,064,313	11/20/62	Butler	18	57	
	3,328,259	6/27/67	Anderson	167	84	
	3,387,061	6/4/68	Smith, et al.	260	874	
	4,141,973	2/27/79	Balazs	424	180	
	4,713,243	12/15/87	Schiraldi, et al.	424	676	
	4,983,585	1/8/91	Pennell, et al.	514	57	
	5,017,229	5/21/91	Burns, et al.	106	162	
	5,156,839	10/20/92	Pennell, et al.	424	78.37	
	5,532,221	7/2/96	Huang, et al.	514	053	
	4,853,374	8/1/89	Allen	514	57	
	5,068,225	11/26/91	Pennell, et al.	514	57	
	4,937,270	6/26/90	Hamilton, et al.	514	777	
	4,684,558	8/4/87	Keusch, et al.	428	40	
	5,080,893	1/14/92	Goldberg, et al.	514	57	
	5,140,016	8/18/92	Goldeberg, et al.	514	57	
	5,354,790	10/11/94	Keusch, et al.	523	300	
	5,266,326	11/30/93	Barry, et al.	424	423	
	4,616,644	10/14/86	Saferstein, et al.	128	156	
	4,024,073	5/17/77	Shimuzu, et al.	252	316	



## U.S. PATENTS

Examiner Initial	Patent Number	Issue Date	First Named Inventor	Class	Subclass	Filing Date
	4,141,973	2/27/79	Balazs	424	180	
	4,181,718	1/1/80	Mason, et al.	424	180	
	4,442,258	4/10/84	Sumakawa, et al.	524	767	
	4,768,523	9/6/88	Cahalan, et al.	128	785	
	4,772,419	9/20/88	Malson, et al.	252	315.1	
	4,937,254	6/26/90	Sheffield, et al.	514	420	
	5,093,319	3/3/92	Higham et al.	514	55	
	5,532,221	7/2/96	Huang, et al.	514	53	
	5,681,873	10/28/97	Norton, et al.	523	115	
	4,610,863	9/9/86	Tewari et al.	423	338	
	5,681,873	10/28/97	Norton et al.	523	115	
	4,937,270	6/26/90	Hamilton et al.	514	777	
	5,906,997	5/25/99	Schwartz et al.	514	781	
	6,017,301	1/25/00	Schwartz et al.	547	781	
	5,800,832	9/1/98	Tapolsky et al.	424	449	
	5,066,709	11/19/91	Chaudhuri et al.	524	516	
	5,462,749	10/31/95	Rencher	424	484	
	5,985,312	11/16/99	Jacob et al.	424	434	
	5,955,096	9/21/99	Santos et al.	424	434	
	5,968,500	10/19/99	Robinson	424	78.08	
	5,874,417	2/23/99	Prestwich et al.	514	54	



### U.S. PATENT PUBLICATIONS

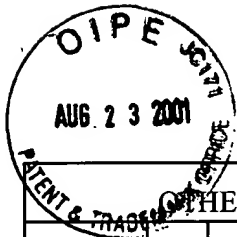
Examiner Initial		Patent Application Publication Number	Publication Date	Applicant

### PENDING U.S. PATENT APPLICATIONS

Examiner Initial		Application Number	Filing Date	First Named Inventor	Petition to Expunge? Yes   No

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document Number	Publication Date	Country	Class	Subclass	Translation Yes   No
		0 264 719 A2	4/27/88	EPO			
		0 193 510 A1	9/3/86	EPO			
		0 138 572 A2	4/24/85	EPO			
		0 265 561 A1	10/27/86	EPO			
		WO 84/03302	8/30/84	WIPO			
		WO 86/00912	2/13/86	WIPO			
		WO 89/02445	3/23/89	WIPO			
		WO 90/10020	9/7/90	WIPO			
		0 581 581 A2	2/2/94	EPO			



## OTHER DOCUMENTS (Include author (if any), title, publisher and place of publication, date and pertinent pages)

	Elkins, et al., <i>Adhesion prevention by solutions of sodium carboxymethylcellulose in the rat. I.</i> Fertility and Sterility, Vol. 41, No. 6, 926-928, June 1984
	Elkins, et al., <i>Adhesion prevention by solutions of sodium carboxymethylcellulose in the rat. II.</i> Fertility and Sterility, Vol. 41, No. 6, 929-932, June 1984
	Wiseman, <i>Polymers for the Prevention of Surgical Adhesions</i> , Johnson & Johnson Medical, Inc., Arlington, Texas, 369-421
	Merrill, <i>Poly(Ethylene Oxide) and Blood Contact, A Chronicle of One Laboratory</i> , 199-229
	Chaikof, <i>Platelet Interaction with Poly(ethylene Oxide) Networks</i> , AIChE Journal, Vol. 36, No. 7, 994-1002, July 1990
	Bottenberg, et al., <i>Development and Testing of Bioadhesive, Fluoride-containing Slow-release Tablets for Oral Use</i> , J. Pharm. Pharmacol., 43:457-464, 1991
	Amiji, <i>Permeability and blood compatibility properties of chitosan-poly(ethylene oxide) blend membranes for haemodialysis</i> , Biomaterials, 16, 593-599, 1995
	Dieckman, et al., <i>Carboxymethylcellulose in the Free Acid Form</i> , Industrial and Engineering Chemistry, Vol. 45, No. 10, 2287-2290
	Gurny, et al., <i>Bioadhesive intraoral release systems: design, testing and analysis</i> , Biomaterials, Vol. 5, 336-340, 1984
	Chen, et al., <i>Compositions Producing Adhesion Through Hydration</i> , 163-181
	Kulicke, et al., <i>Characterization of aqueous carboxymethylcellulose solutions in terms of their molecular structure and its influence on rheological behavior</i> , Polymer, Vol. 37, Number 13, 2723-2731, 1996
	Ohno, et al., <i>Interpolymer Complex Formation of Polysaccharides with Poly(ethylene oxide) or Poly(1-vinyl-2-pyrrolidone) through Hydrogen Bond</i> , Makromol. Chem., Rapid Commun., 2, 511-515, 1981
	Acqualon, <i>Sodium Carboxymethylcellulose, Physical and Chemical Properties</i> , Hercules, Inc., 1-27
	Didishelm, et al., <i>Hematologic and Coagulation Studies in Various Animal Species</i> , J. Lab. & Clin. Med., 866-875, June 1959
	Harris, et al., <i>Analysis of the Kinetics of peritoneal adhesion formation in the rat and evaluation of potential antiadhesive agents</i> , Surgery, 663-669, June 1995
	Becker, et al., <i>Prevention of Postoperative Abdominal Adhesions by a Sodium Hyaluronate-based Bioresorbable Membrane: A Prospective, Randomized, Double-Blind Multicenter Study</i> , Journal of American College of Surgeons, Vol. 183, 297-306, October 1996
	INTERCEED (TC7) Adhesion Barrier Study Group, <i>Prevention of postsurgical adhesions by INTERCEED (TC7), * an absorbable adhesion barrier: a prospective, randomized multicenter clinical study</i> , Fertility and Sterility, Vol. 51, No. 6, 933-938, June 1989
	Diamond, et al., <i>Reduction of adhesions after uterine myomectomy by Seprafilm* membrane (HAL-F): a blinded, prospective, randomized, multicenter clinical study</i> , Fertility and Sterility, Vol. 66, No. 6, 904-910, December 1996
	Sung, et al., <i>Swelling properties of hyaluronic acid ester membranes</i> , Journal of Membrane Science, 92, 157-167, 1994
	Braun, <i>Poly (Ethylene Oxide)</i> , Union Carbide Corporation, Union Carbide Chemical and Plastics Company, Inc., Specialty Chemicals Division, (Reprinted from Handbook of Water-Soluble Gums and Resins), pp. 19-1 - 19-33
	<i>Polyox Water-soluble Resins</i> , Association Compounds, Union Carbide Chemicals Division, p. 22, 1991



OTHER DOCUMENTS (Include author (if any), title, publisher and place of publication, date and pertinent pages)

	<i>Sepra film™ Bioresorbable Membrane, Product Monograph for the Reduction of Postsurgical Adhesions</i> , Genzyme Corporation, 1-29, 1996
	Kitano, et al., <i>Viscous Carboxymethylcellulose in the Prevention of Epidural Scar Formation</i> , Spine, Vol. 16, No. 7, July 1991
	<i>Hercules Cellulose Gum, Sodium Carboxymethylcellulose, Chemical and Physical Properties</i> , Hercules, Inc., 1-31, 1984
	Takayma, et al., <i>Effect of Interpolymer Complex Formation on Bioadhesive Property and Drug Release Phenomenon of Compressed Tablet Consisting of Chitosan and Sodium Hyaluronate</i> , Chem. Pharm. Bull., 38(7), 1993-1997, 1990
	Aurora, et al., <i>Pathology of Peritoneal Adhesions - An Experimental Study</i> , Indian J. Med. Res., 62, 4, 539-544, April 1974
	Harland, et al., <i>Polyelectrolyte Gels, Properties, Preparation, and Applications</i> , American Chemical Society Symposium Series, November 11-16, 1990, 480
	Feddersen, et al., <i>Sodium Carboxymethylcellulose</i> , Industrial Gums, Polysaccharides and Their Derivatives, Third Edition, 537-579, 1993
	Steizer, et al., <i>Carboxymethylcellulose</i> , Handbook of Water-Soluble Gums and Resins Chapter 4, pp. 4-1 - 4-28, 1980
	Danishefsky, et al., <i>Conversion of Carboxyl Groups of Mucopolysaccharides into Amides of Amino Acid Esters</i> , Carbohydr. Res., 16, 199-205, 1971
	Tsuchida, et al., <i>Interactions Between Macromolecules in Solution and Intermacromolecular Complexes</i> , Advance Polymer Science, 45-122, 1982
-	Anseth, et al., <i>Mechanical properties of hydrogels and their experimental determination</i> , Biomaterials, 17, 1647-1657, 1996
-	Kofinas, et al., <i>Development of methods for quantitative characterization of network morphology in pharmaceutical hydrogels</i> , Biomaterials, Vo. 18, No. 20, 1361-1369
-	Agrawal, et al., "Technique to Control pH in Vicinity of Biodegrading PLA-PGA Implants, <i>John Wiley &amp; Sons, Inc.</i> , 1997, pp. 105-114.
-	Hunt, et al., "Silica Aerogel, A Transparent High Performance Insulator," <i>Proceedings of the International Solar Energy Society World Congress</i> , Sept. 13-18, 1987, Hamburg, West Germany, pp. 1-5.
-	Tewari, et al., "Microstructural Studies of Transparent Silica Gels and Aerogels," <i>Proceedings of the 1986 Spring Meeting of the Materials Research Society</i> , April 15-19, 1986, Palo Alto, CA., pp. 1-11.
-	Hunt, et al., "Process Considerations in Monolithic Aerogels," <i>Materials Research Society</i> , 1988, Materials Research Society Symposium, Vol. 121, pp. 679-684.
-	Lenaerts, Ph.D., et al., "Bioadhesive Drug Delivery Systems," <i>CRC Press, Inc.</i> , 1990, pp. 25-168.
-	Lofftus, et al., "Colloidal and Kinetic Principles of Sol-Gel Processing," <i>Advanced Materials '90</i> , March, 1990.

Examiner

Date Considered

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*1 = Copy not submitted because it was submitted in prior application SN    /    , filed    , 20    , relied on under 35 USC §120.

\*2 = Copy not submitted because it was submitted in prior application SN    /    , filed    , 20    , relied on under 35 USC §120.